

L Number	Hits	Search Text	DB	Time stamp
1	2	("6468300").PN.	USPAT; US-PGPUB; EPO; JPO; DERWENT	2003/01/20 08:57
2	2	("6254627").PN.	USPAT; US-PGPUB; EPO; JPO; DERWENT	2003/01/20 10:07
3	27	("4400833"   "4502159"   "4801299"   "5383928"   "5489298"   "5512291"   "5549663"   "5556414"   "5571173"   "5575818"   "5584876"   "5599307"   "5628786"   "5641373"   "5653743"   "5653747"   "5667523"   "5674298"   "5693085"   "5707385"   "5723004"   "5741326"   "5782914"   "5934283"   "5980565"   "5997573"   "6117166").PN.	USPAT	2003/01/20 09:37
4	3368	((623/1.11,1.13,1.14,1.23,1.44,1.27,23.7,23.7, or (606/153,194,195)).CCLS.	USPAT; US-PGPUB; EPO; JPO; DERWENT	2003/01/20 10:46
5	226	((623/1.11,1.13,1.14,1.23,1.44,1.27,23.7, or (606/153,194,195)).CCLS.) and tissue with (thickness or thick)	USPAT; US-PGPUB; EPO; JPO; DERWENT	2003/01/20 10:48

Document ID	Kind	Serial Number	Page
1	US	3951138	USP19760420 9
2	US	4233981	USP19801118 5
3	US	4300243	USP19811117 4
4	US	4355426	USP19821026 12
5	US	4366819	USP19830104 15
6	US	4476863	USP19841016 9
	US	4674506	USP19870301 10
8	US	4681588	USP19870721 9
9	US	4695281	USP19870922 5
10	US	4743252	USP19880510 8
11	US	4813964	USP19890321 4
12	US	4813958	USP19890321 4
13	US	4836204	USP19890606 8
14	US	4846834	USP19890711 16
15	US	4861330	USP19890829 9
16	US	4902508	USP19900220 6
17	US	4927410	USP19900522 13
18	US	4956178	USP19900911 7
19	US	4957499	USP19900918 11
20	US	4964863	USP19901023 6
21	US	4986832	USP19910122 8
22	US	5005591	USP19910409 8
23	US	5011493	USP19910430 5
24	US	5024671	USP19910618 7
25	US	5074878	USP19911224 9
26	US	5192289	USP19930309 10
27	US	5217494	USP19930608 9
28	US	5222963	USP19930629 14
29	US	5234447	USP19930810 8
30	US	5250058	USP19931005 14
31	US	5282859	USP19940201 14
32	US	5304122	USP19940419 18
33	US	5304121	USP19940419 16
34	US	5308356	USP19940503 22
35	US	5314471	USP19940524 23
36	US	5330486	USP19940719 25
37	US	5344454	USP19940906 22
38	US	5346501	USP19940913 13

US-PAT-NO: 4674506

DOCUMENT-IDENTIFIER: US 4674506 A

TITLE: Surgical anastomosis stent

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## Brief Summary Text - BSTX (7):

Although this refinement is a procedure still in common use because of its low cost-benefit ratio, it is accompanied by particularly undesirable aspects. First, the refinement traumatizes the lumen, adjoining muscle and connective tissue layers at two sites. Commonly, a 0.037 inch diameter stent of Silastic tubing is pushed through a lumen having an interior diameter as small as 0.025 inches and outwardly through a ~~tissue~~ wall thickness of about 0.040 inches.

Second, the passage of the stent through the cavity incision serves as a track for the entrance of infection. Moreover, evidence exists which shows that obstructions occur at sites where the stent exits through the walls of the vas deferens.

## Current US Original Classification - CCOR (1):

6067153

Document I	Reco	Issue Date	Page
1 US 3951138	USP	19760420	9 D
2 US 4233981	USP	19801118	5 D
3 US 4300243	USP	19811117	4 P
4 US 4355426	USP	19821026	12 P
5 US 4366819	USP	19830104	15 A
6 US 4476863	USP	19841016	9 S
7 US 4674506	USP	19870623	10 S
8 US 4681588	USP	19870721	9 B
9 US 4695281	USP	19870922	5 M
10 US 4743252	USP	19880510	8 C
11 US 4813964	USP	19890321	4 C
12 US 4813958	USP	19890321	4 C
13 US 4836204	USP	19890606	8 M
14 US 4846834	USP	19890711	16 M
15 US 4861330	USP	19890829	9 C
16 US 4902508	USP	19900128	6 C
17 US 4927410	USP	19900522	13 M
18 US 4956178	USP	19900911	7 T
19 US 4957499	USP	19900918	11 S
20 US 4964863	USP	19901023	6 D
21 US 4986832	USP	19910122	8 A
22 US 5005591	USP	19910409	8 S
23 US 5011493	USP	19910430	5 M
24 US 5024671	USP	19910618	7 M
25 US 5074878	USP	19911224	9 T
26 US 5192289	USP	19930309	10 A
27 US 5217494	USP	19930608	9 T
28 US 5222963	USP	19930629	14 P
29 US 5234447	USP	19930810	8 S
30 US 5250058	USP	19931005	14 A
31 US 5282859	USP	19940201	14 C
32 US 5304122	USP	19940419	18 M
33 US 5304121	USP	19940419	16 D
34 US 5308356	USP	19940503	22 P
35 US 5314471	USP	19940524	23 T
36 US 5330486	USP	19940719	25 L
37 US 5344454	USP	19940906	22 C
38 US 5346501	USP	19940913	13 L
39 US 5354329	USP	19941011	12 V
40 US 5364389	USP	19941115	13 M
41 US 5366462	USP	19941122	10 M

US-PAT-NO: 4902508

DOCUMENT-IDENTIFIER: US 4902508 A

TITLE: Tissue graft composition

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Detailed Description Text - DETX (7):

The tissue graft material of this invention is prepared by abrading intestinal tissue to remove the outer layers including both the tunica serosa and the tunica muscularis (layers B and C in FIG. 1) and the inner layers including at least the luminal portion (layer G) of the tunica mucosa (layers E through G in FIG. 1). Under conditions of mild abrasion the tunica mucosa is delaminated between the stratum compactum (layer F) and the lamina propria of layer G. More particularly, following removal of any mesenteric tissues from the intestinal segment utilizing, for example, Adson-Brown forceps and Metzenbaum scissors, the tunica serosa and the tunica muscularis (the outer tissue layers) are delaminated from the intestinal segment by abrasion using a longitudinal wiping motion with a scalpel handle and moistened gauze. Following eversion of the intestinal segment, the luminal portion of the tunica mucosa is delaminated from the underlying tissue using the same wiping motion. Care is taken to prevent perforation of the submucosa. Also, any tissue "tags" from the delaminated layers remaining on the graft surface are removed. Optionally, the intestinal segment may be everted first, then stripped of the luminal layers, then reinserted to its original orientation for removal of the tunica serosa and the tunica muscularis. The graft material is a whitish, translucent tube of tissue approximately 0.1 mm thick typically consisting of the tunica submucosa with the attached lamina muscularis mucosa and stratum compactum. For vascular graft preparation, the prepared graft is everted to its original orientation so that the stratum compactum serves as the luminal surface of the graft.

Current US Cross Reference Classification - CCXR (1):

525723072

Document I	Kind	Number	Date	Page
1 US 6117166	USP	20000912	8	App
2 US 5997573	USP	19991207	14	Ste
3 US 5980565	USP	19991109	7	San
4 US 5934283	USP	19990810	9	Pub
5 US 5782914	USP	19980721	6	Met
6 US 5741326	USP	19980721	1	Lit
7 US 5723004	USP	19980303	13	Exp
8 US 5707385	USP	19980113	12	Dru
9 US 5693085	USP	19971202	15	Ste
10 US 5674298	USP	19971007	11	Cal
11 US 5667523	USP	19970916	15	Dua
12 US 5653747	USP	19970805	8	Lum
13 US 5653743	USP	19970805	9	Hyp
14 US 5641373	USP	19970624	13	Met
15 US 5628786	USP	19970513	10	Rad
16 US 5599307	USP	19970204	16	Cat
17 US 5584876	USP	19961217	8	Cel
18 US 5575818	USP	19961119	13	End
19 US 5571173	USP	19961105	19	Gra
20 US 5556414	USP	19960917	14	Com
21 US 5549663	USP	19960827	8	End
22 US 5512291	USP	19960430	14	Met
23 US 5489298	USP	19960206	46	Rap
24 US 5383928	USP	19950124	11	Ste
25 US 4801299	USP	19890131	10	Bod
26 US 4502159	USP	19850305	7	Tub
27 US 4400833	USP	19830830	11	Mea

sheet to maintain the cover in a wrapped configuration about the stent during deployment of the assembly. Also, there remains a need for an endoprosthetic assembly including a stent cover that prevents undesirable tissue growth through the stent openings yet provides sufficient porosity for desirable cellular ingrowth and capillary formation. Finally, there remains a need for an endoprosthetic assembly stent covering providing the above advantages and that can be used with existing stents.

#### SUMMARY OF THE INVENTION

The present invention provides an endoprosthetic assembly for percutaneous deployment and implantation within a body passageway. The endoprosthetic assembly includes a stent and a stent cover. The assembly is affixed to a balloon portion of a balloon catheter for deployment to a treatment site within a patient's vasculature.

The stent comprises a radially expandable cylindrical frame while the stent cover comprises a thin walled, single layer polyester woven sleeve having a length just less than a length of the stent. The inner diameter of the cover is matched to the desired, expanded outer diameter of the stent. Normally, the stent cover is wrapped around the stent when the stent is in an unexpanded constricted configuration and is thermally set in the wrapped configuration. After being thermally set, an outer surface of the wrapped cover has a uniform and smooth cylindrical shape. The thermally set cover remains in the wrapped configuration during deployment of the endoprosthetic assembly to the treatment site.

The unwrapped diameter of the stent cover and the expanded diameter of the stent must be matched to the size of the blood vessel that is to be treated. As the balloon of the balloon catheter is expanded, the stent expands and stent cover correspondingly unwraps. The stent is expanded until it is fully seated compressing the unwrapped cover against the blood vessel intraluminal wall.

The stent cover remedies the problems associated with the open spaces of the stent frame, while its uniform cylindrical shape after thermal setting minimizes the increase in the assembly's outer diameter due to the cover. The outward radial force necessary to unwrap the cover is less than the radial force necessary to expand the stent. Further, once the cover is unwrapped or open, it does not have a tendency to return to its wrapped configuration and therefore does not tend to apply an inwardly directed radial force on the expanded stent which could cause the stent to collapse.

The cross sectional profile of the endoprosthetic assembly of the present invention allows a significantly smaller introducer passageway to be used than was previously possible using traditional stent covers. Further, the uniformity in the outer surface of the wrapped cover eliminates the need for a deployment sheath and the attendant increase in cross section of the assembly such a sheath would cause.

To fabricate the endoprosthetic assembly of the present invention, polyester fiber is woven into a tubular shaped sleeve. Preferably, the sleeve is comprised of a single ply polyester material having a thickness of approximately 0.004 inches. The preferred polyester is polyethylene terephthalate (PET). The cover is cut from the woven sleeve. The cover is cut to a length just slightly less than a length of the selected stent the cover will be used with. The inner diameter of the cover is selected to match the outer diameter of the stent when the stent is expanded to a desired diameter within a blood vessel.

The stent cover is affixed to the stent with a single tie stitch extending through the cover and looped around a

support member of the stent frame. The cover is then wrapped tightly around the stent while the stent is in its unexpanded configuration.

The stent and wrapped cover are inserted into a piece of heat shrink tubing. The tubing is sized to fit snugly over the cover. Then the endoprosthetic assembly is exposed to an elevated temperature causing the heat shrink tubing to shrink and radially compress the cover. The heat and the heat shrink tubing set the cover in its wrapped configuration. The heat shrink tubing is then peeled off. The stent is positioned on the balloon portion of a balloon catheter and the stent is crimped onto the catheter balloon portion.

During deployment, the stent cover remains in its thermally set, wrapped configuration until during implantation the inner surface of the cover overlying the stent is subjected to the outwardly directed radial forces extended by the expanding stent. A stent cover fabricated of woven PET polyester exhibits the advantages of so-called non-compliant stents, namely, good long term fatigue resistance to pulsatile pressure, resistance to smoothening and leaks and good healing characteristics.

These and other advantages and features of this invention will be clearly understood through consideration of the following detailed description of the invention in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of an endoprosthetic assembly of the present invention and a delivery assembly including a balloon catheter for percutaneous deployment of the endoprosthetic assembly;

FIG. 2 is a cross section view of the endoprosthetic assembly of FIG. 1 including a stent and a stent cover partially wrapped around the stent;

FIG. 3 is a cross section view of the endoprosthetic assembly of FIG. 1 with the stent cover completely wrapped around the stent;

FIG. 4 is a cross section view of the endoprosthetic assembly of FIG. 1 with a section of heat shrink tubing overlying the stent cover;

FIG. 5 is a cross section view of the endoprosthetic assembly of FIG. 1 mounted on the balloon catheter with the stent cover thermally set in its wrapped configuration and the section of heat shrink tubing stripped off;

FIG. 6 is a perspective view of the endoprosthetic assembly of FIG. 1 mounted on the balloon catheter within a patient's blood vessel;

FIG. 7 is a side elevation view of the endoprosthetic assembly of FIG. 1 mounted on the balloon catheter and positioned within a partially occluded portion of a blood vessel;

FIG. 8 is a cross section view of the endoprosthetic assembly and the balloon catheter as seen from a plane indicated by the line 8-8 in FIG. 7;

FIG. 9 is a side elevation view of the endoprosthetic assembly of FIG. 1 mounted on the balloon catheter with a balloon portion of the catheter inflated expanding the stent, unwrapping stent cover and increasing a size of the opening through the blood vessel; and

FIG. 10 is a cross section view of the endoprosthetic assembly and the balloon catheter as seen from a plane indicated by the line 10-10 in FIG. 9.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

##### I Configuration and Use of the Endoprosthetic Assembly

Turning to the drawings, the present invention provides for an endoprosthetic assembly 10 including a stent 12 and

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1 US 6117166	USP	20000912	8	App
2 US 5997573	USP	19991207	14	Ste
3 US 5980565	USP	19991109	7	San
4 US 5934283	USP	19990810	9	Pub
5 US 5782914	USP	19980721	6	Met
6 US 5741326	USP	19980421	11	Low
7 US 5723004	USP	19980303	13	Exp
8 US 5707385	USP	19980117	11	Exs
9 US 5693085	USP	19971202	15	Ste
10 US 5674298	USP	19971007	11	Cal
11 US 5667523	USP	19970916	15	Dua
12 US 5653747	USP	19970805	8	Lum
13 US 5653743	USP	19970805	9	Hyp
14 US 5641373	USP	19970624	13	Met
15 US 5628786	USP	19970513	10	Rad
16 US 5599307	USP	19970204	16	Cat
17 US 5584876	USP	19961217	8	Cel
18 US 5575818	USP	19961119	13	End
19 US 5571173	USP	19961105	19	Gra
20 US 5556414	USP	19960917	14	Com
21 US 5549663	USP	19960827	8	End
22 US 5512291	USP	19960430	14	Met
23 US 5489298	USP	19960206	46	Rap
24 US 5383928	USP	19950124	11	Ste
25 US 4801299	USP	19890131	10	Bod
26 US 4502159	USP	19850305	7	Tub
27 US 4400833	USP	19830830	11	Mea

rality of apertures close tightly so that no therapeutic drug can pass therethrough. The expandable membrane is then rolled onto the balloon portion of the catheter to form a cylindrical configuration and is delivered intraluminally as described above. The flat sheet is rolled into a cylinder and the edges are joined by welding, adhesive, etc. The balloon portion of the catheter is expanded thereby expanding the expandable membrane and forcing the therapeutic drug through the plurality of apertures and into contact with the vessel wall at the site of the injured or diseased area. After the therapeutic drug has been delivered, the balloon portion of the catheter is deflated and the catheter and expandable membrane are withdrawn from the vasculature. Instead of forming the expandable membrane from flat sheets, this embodiment may also be achieved with two tubular members, one within the other, to form a cavity between the layers. The ends are sealed and laser micro-holes are drilled into the outer layer to allow the therapeutic drug to pass therethrough. The tubular members also may have a drug incorporated in the polymer material in the form of a matrix which allows the drug to diffuse into the vessel wall over time.

In another embodiment of the invention, the expandable membrane is in the form of a flat sheet and having a thickness in the range of 0.002-0.020 inches. A plurality of micro-pockets are drilled into the outer surface of the expandable membrane, but are not drilled all the way through it to form a hole. The micro-pockets are drilled while the membrane is in its stretched position. Thereafter, a therapeutic drug is loaded into the various micro-pockets and the membrane is relaxed so that the pockets close with the therapeutic drug inside. The elastic membrane can then be rolled into a cylindrical form and mounted on a catheter for delivery to the diseased or injured area. When the expandable membrane is expanded by the balloon portion of the catheter, the micro-pocket open and the therapeutic drug is delivered to the diseased or injured area. After the therapeutic drug has been delivered, the balloon portion of the catheter is deflated and the catheter and expandable membrane are withdrawn from the patient.

In yet another embodiment of the invention, an intravascular stent is mounted on the balloon portion of a catheter so that it may be implanted in a conventional manner within the vasculature. An expandable membrane having a therapeutic drug contained therein, in the form of a matrix, is mounted on the outer surface of the stent and the catheter, stent, and expandable membrane are delivered intraluminally to the injured or diseased area. As the balloon is expanded, it forces the stent radially outwardly along with the expandable membrane and into contact with the vessel wall. The balloon portion of the catheter is then deflated and the catheter and balloon withdrawn from the vasculature leaving the intravascular stent and expandable membrane implanted at the injured or diseased area. Thereafter, the therapeutic drug will diffuse from the matrix into the vessel wall to provide treatment in an effort to reduce the incidence of restenosis.

In both the reservoir or matrix form of drug delivery, the therapeutic drug may be retained in various structures including microspheres, sheets, tubes and so forth.

The expandable membrane of the present invention may be deployed in a body lumen through a variety of devices, including, but not limited to, balloon catheters and specialized devices which can deliver a stent within a body lumen. These and other advantages of the invention will become more apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

#### 4 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of the expandable membrane of the invention prior to rolling into a cylindrical configuration;

FIG. 2A is a perspective view of the expandable membrane of FIG. 1 in its rolled up condition with its first edge attached to the second edge in an overlapping relationship;

FIG. 2B is a perspective view depicting the elastic membrane in a hollow tubular form that is seamless;

FIG. 3 depicts a partial cross-sectional view of an elevation of a rapid exchange catheter system having a stent mounted on a balloon with the expandable membrane mounted over the stent;

FIG. 4A is a partial cross-sectional view depicting an over-the-wire catheter system having a stent mounted on the balloon portion of the catheter and an expandable membrane mounted over the stent;

FIG. 4B is a partial cross-sectional view of a perfusion-type catheter system having a stent mounted on the balloon portion of the catheter and an expandable membrane over the stent;

FIG. 5 is an elevational view depicting the rapid exchange catheter system of FIG. 3 wherein the stent mounted on the balloon portion of the catheter has a specific configuration and the expandable membrane is mounted over the stent;

FIG. 5A is a cross-sectional view taken along line 5A—5A depicting the expandable membrane over the stent and balloon portion of the catheter;

FIG. 6 is a partial cross-sectional view of the catheter delivery system and stent with the membrane mounted on the stent being transluminally delivered within the patient's vasculature;

FIG. 7 is a partial cross-sectional view of the balloon portion of the catheter expanding the stent and the expandable membrane within the patient's vasculature;

FIG. 8 is a partial cross-sectional view of an intravascular stent and an expandable membrane implanted against the patient's vessel wall;

FIG. 8A is a cross-sectional view taken along line 8A—8A depicting the expandable membrane and stent expanded and in contact with the vessel wall;

FIG. 9 is a perspective view of the expandable membrane wherein the first layer and the second layer are spaced apart prior to affixing the edges to each other;

FIG. 10 is the expandable membrane of FIG. 9 wherein the first layer and the second layer have been joined and the plurality of holes are closed since the membrane is in its relaxed condition;

FIG. 11 is a perspective view of the expandable membrane of FIG. 10 in its rolled up condition and in an unexpanded state with the plurality of micro-holes tightly closed thereby containing the drug within the drug filled reservoir;

FIG. 11A is a perspective view of an expandable membrane having an inner tube and an outer tube with a drug receiving cavity in between the two tubes;

FIG. 12 is a perspective view of the expandable membrane having a plurality of micro-pockets for receiving a therapeutic drug; and

FIG. 13 is a perspective view of the expandable membrane of FIG. 12 in its rolled up condition in a cylindrical form with the micro-pockets tightly closed and in an unexpanded condition.

#### 5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

During PTCA procedures it is common to use a dilatation catheter to expand a diseased area to open the patient's

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	Document ID	Issue Date	Page	Title
1	US 4338300 A	U 19820706	5	Use of puri
2	US 4388735 A	U 19830621	12	Low profile
3	US 4774957 A	U 19881004	13	Material fo
4	US 4958008 A	U 19900918	9	Process for
5	US 5012503 A	U 19910430	6	Method for
	US 5163955 A	U 19921117	44	Rapid assem
7	US 5326371 A	U 19940705	43	Rapid assem
8	US 5326370 A	U 19940705	42	Prefabricat
9	US 5344442 A	U 19940906	12	Cardiac val
10	RU 2033112 C	D 19950420		Heart repai
11	US 5423887 A	U 19950613	43	Rapid assem
12	US 5489298 A	U 19960208	46	Rapid assem
13	US 5500015 A	U 19960319	11	Cardiac val
14	US 5531784 A	U 19960702	41	Test device
15	US 5571174 A	U 19961105	41	Method of a
16	US 5584878 A	U 19961217	41	Test device
17	US 5647380 A	U 19970715	17	Method of m
18	US 5653749 A	U 19970805	42	Prefabricat
19	US 5662705 A	U 19970902	42	Test device
20	US 5758664 A	U 19980602	26	Method of m
21	US 6063115 A	U 20000516	8	Cardiac ass
22	US 6086526 A	U 20000711	10	Cardiac ass
23	US 6214055 B1	U 20010410	8	Method and
24	US 6254627 B1	U 20010703	9	Non-thrombo
25	US 2001002337	U 20010920	10	Processing
26	US 6328763 B1	U 20011211	10	Optimized o
27	US 6334873 B1	U 20020101	20	Heart valve
28	US 2002002623	U 20020228	19	Heart valve
29	US 6378221 B1	U 20020430	27	Systems and
30	US 2002012378	U 20020905	10	Stent cover
31	US 2002015196	U 20021017	4	Stent cover
32	US 6468313 B1	U 20021022	14	Implants an
33	US 6468300 B1	U 20021022	5	Stent cover
34	US 2002015727	U 20021031	25	Systems and
35	US 2002019388	U 20021219	14	Implants an
36	US 2003002824	U 20030206	13	Method of c
37	US 6534004 B2	U 20030318	10	Processing
38	US 6553681 B2	U 20030429	26	Methods for

US-PAT-NO: 5163955

DOCUMENT-IDENTIFIER: US 5163955 A

\*\*See image for Certificate of Correction\*\*

TITLE:

Rapid assembly, concentric mating stent, tissue heart  
valve with enhanced clamping and tissue alignment

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## Detailed Description Text - DETX (44):

With respect to the dimension identified with numeral 18, this dimension is the nominal distance between the mated stents along a channel which extends down the sides and along the bottoms of the stents. It has been found that if pericardial tissue, the dimension is preferably about 0.020 ~~inches~~ in order to accommodate the ~~thickness~~ of the tissue and the ~~thickness~~ of the Dacron fabric coverings, although for other tissue types such as fascia lata, other dimensions may be preferable.

## Detailed Description Text - DETX (63):

Turning now to the tissue 2 in FIG. 1, this tissue is preferably autogenous tissue, such as pericardial tissue, but it may also be fascia lata, rectus fascia (or sheath), or vein tissue. These tissue sources are all relatively flimsy and difficult to handle. This is because this tissue once harvested will have a thickness of about 10-12 mils. By comparison, bovine pericardium is about 15-20 ~~mil~~ thick. Therefore, as will be described in more detail further on, after the tissue is harvested, the tissue is usually quick-fixed dipping it in 0.6% glutaraldehyde solution. This serves to toughen it, and make it easier to handle.

## Detailed Description Text - DETX (105):

The cutting pad 78 is preferably a thin, i.e., 0.025 inch or less, sheet of Teflon or the like, and is configured to provide an appropriate amount of resiliency against the razor sharp blade of the die. The thickness of the pad is determined by the extent to which blade 33 extends above the upper surface of the cutting die 36 and by the thickness of the tissue used. In the example discussed earlier, the blade extension is 35 mils. and human 25 pericardial tissue may be about 10 ~~mil~~ thick. The thickness of the pad should be the difference, i.e., 25 mils, in this example. The cutting pad functions to limit the blade penetration into the tissue and the base on which it is resting.

Document ID	US	Issue Date	Pag	Title
1	US 4338300 A	U 19820706	5	Use of puri
2	US 4388735 A	U 19830621	12	Low profile
3	US 4774957 A	U 19881004	13	Material fo
4	US 4958008 A	U 19900709	9	Process for
5	US 5012503 A	U 19910430	6	Method for
6	US 5163955 A	U 19921117	46	Rapid assem
7	US 5326371 A	U 19940705	43	Rapid assem
8	US 5326370 A	U 19940705	42	Prefabricat
9	US 5344442 A	U 19940906	12	Cardiac val
10	RU 2033112 C	D 19950420		Heart repai
11	US 5423887 A	U 19950613	43	Rapid assem
12	US 5489298 A	U 19960206	46	Rapid assem
13	US 5500015 A	U 19960319	11	Cardiac val
14	US 5531784 A	U 19960702	41	Test device
15	US 5571174 A	U 19961105	41	Method of a
16	US 5584878 A	U 19961217	41	Test device
17	US 5647380 A	U 19970719	17	Method of m
18	US 5653749 A	U 19970805	42	Prefabricat
19	US 5662705 A	U 19970902	42	Test device
20	US 5758664 A	U 19980602	26	Method of m
21	US 6063115 A	U 20000516	8	Cardiac ass
22	US 6086526 A	U 20000711	10	Cardiac ass
23	US 6214055 B1	U 20010410	8	Method and
24	US 6254627 B1	U 20010703	9	Non-thrombo
25	US 2001002337	U 20010920	10	Processing
26	US 6328763 B1	U 20011211	10	Optimized q
27	US 6334873 B1	U 20020101	20	Heart valve
28	US 2002002623	U 20020228	19	Heart valve
29	US 6378221 B1	U 20020430	27	Systems and
30	US 2002012378	U 20020905	10	Stent cover
31	US 2002015196	U 20021017	4	Stent cover
32	US 6468313 B1	U 20021022	14	Implants an
33	US 6468300 B1	U 20021022	5	Stent cover
34	US 2002015727	U 20021031	25	Systems and
35	US 2002019388	U 20021219	14	Implants an
36	US 2003002824	U 20030206	13	Method of c
37	US 6534004 B2	U 20030318	10	Processing
38	US 6553681 B2	U 20030429	26	Methods for

US-PAT-NO: 4958008

DOCUMENT-IDENTIFIER: US 4958008 A

\*\*See image for Certificate of Correction\*\*

TITLE:

Process for crosslinking of collagen by introduction of azide groups as well as tissues and biomaterials obtained by use of the process

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## Detailed Description Text - DETX (51):

When introduction of the azide groups is performed in the absence of sodium chloride, the hydrochloric acid causes, at the end of esterification, a swelling of the tissue; the latter then becomes thicker and translucent. The swelling corresponds to a limited dissolution of the tissue since there are numerous intermolecular and intramolecular bonds preventing a total dissolution of the tissue. At the end of esterification, the thermal stability of the tissue is that of an acid-soluble collagen (denaturing starting temperature is 36.degree. C., the thickness of the pericardium goes from 0.38 mm to 0.82

	Document ID	NS	Title
1	US 4338300 A	U 19820706 5	Use of purified
	US 4388735 A	U 19880001 13	Low profile prosthetic heart valve
3	US 4774957 A	U 19881004 13	Material for
4	US 4958008 A	U 19900918 9	Process for
5	US 5012503 A	U 19910430 6	Method for
6	US 5163955 A	U 19921117 46	Rapid assem
7	US 5326371 A	U 19940705 43	Rapid assem
8	US 5326370 A	U 19940705 42	Prefabricat
9	US 5344442 A	U 19940906 12	Cardiac val
10	RU 2033112 C	D 19950420	Heart repair
11	US 5423887 A	U 19950613 43	Rapid assem
12	US 5489298 A	U 19960206 46	Rapid assem
13	US 5500015 A	U 19960319 11	Cardiac val
14	US 5531784 A	U 19960702 41	Test device
15	US 5571174 A	U 19961105 41	Method of a
16	US 5584878 A	U 19961217 41	Test device
17	US 5647380 A	U 19970715 17	Method of m
18	US 5653749 A	U 19970805 42	Prefabricat
19	US 5662705 A	U 19970902 42	Test device
20	US 5758664 A	U 19980602 26	Method of m
21	US 6063115 A	U 20000516 8	Cardiac ass
22	US 6086526 A	U 20000711 10	Cardiac ass
23	US 6214055 B1	U 20010410 8	Method and
24	US 6254627 B1	U 20010703 9	Non-thrombo
25	US 2001002337	U 20010920 10	Processing
26	US 6328763 B1	U 20011211 10	Optimized q
27	US 6334873 B1	U 20020101 20	Heart valve
28	US 2002002623	U 20020228 19	Heart valve
29	US 6378221 B1	U 20020430 27	Systems and
30	US 2002012378	U 20020905 10	Stent cover
31	US 2002015196	U 20021017 4	Stent cover
32	US 6468313 B1	U 20021022 14	Implants an
33	US 6468300 B1	U 20021022 5	Stent cover
34	US 2002015727	U 20021031 25	Systems and
35	US 2002019388	U 20021219 14	Implants an
36	US 2003002824	U 20030206 13	Method of c
37	US 6534004 B2	U 20030318 10	Processing
38	US 6553681 B2	U 20030429 26	Methods for

US-PAT-NO: 4388735

DOCUMENT-IDENTIFIER: US 4388735 A

TITLE: Low profile prosthetic xenograft heart valve

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## Detailed Description Text - DETX (5):

It is neither necessary nor possible to give exact shape and dimensional definitions to the leaflets exemplified by leaflet 30, but the configuration may be described, realizing that the truly critical relationship is the interrelationship of the three obtuse truncated triangular portions. The maximum width of the leaflets lies about the midpoint thereof. The height of the leaflet is, of course, of no criticality whatever, however, and so this is merely a general relationship. Thus, the sum of Sa, Sb, and Sc, is approximately equal to one-half of the total vertical height of the leaflet, representing the mean altitude of the obtuse truncated triangle formed by plateau 46 and the converging edge portions 42 and 44 and the base formed by the juncture between top edge with side 34 and side 36 respectively, Sb plus being equal to about 35% plus or minus 3 to 5% of the total height and the sum of Sa, Sb and Sc being about 50% plus or minus around 10% of the total vertical height. The width of the leaflet Wa, measured Sa down from the point 46 is about 85% plus or minus 10% of the maximum width of the leaflet, Sa being around 12 to 17% of the total height. The width Wb measured at Sa plus Sb from the point 46 is about 95% plus or minus about 5% of the maximum width. Sa plus Sb is about 30 to 40%, generally around 35% of the total height. The maximum width is usually at about 45 to 55% of height. The exact width and height ratios depends upon the overall size of the valve and generally will fall within the ranges indicated, although the first definition by function is the best and most meaningful description presently comprehended. In a specific embodiment, the valving member for the size 23 valve is a section of pericardium 0.012 inch thick, with a maximum height of 21 millimeters, a maximum width Wc of 26.5 millimeters, at about 52% of total height, the width of the obtuse triangle is 22.5 millimeters measured at Sa down about 14% of total height from the top, the intermediate width Wb being 25.5 millimeters, Sb, 35% from the top. Again, this is merely one example of one size of a valve and the dimensions are not the critical factor, it is the interrelationship of the top edges of the leaflet which are critical.